

EPA Registration Number 2596-181 Part 2

DATA EXTRACTION REQUEST

Reg # 2596-181 Decision # _____

Description: Revised basic CSF

Material Sent:

- ☐ Electronic Label/Letter Dated _____
(See PPLS for electronic file)
- ☐ Stamped Label Dated _____ (See jacket)
- ☐ Notification Dated _____ (See jacket)
- ☒ New CSF(s) Dated 1-22-2015 (See jacket)
- ☐ Other: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Rita Kumar

Division: RD/IRB

Phone: 703-308-8291

Date: 6-22-2015

Kumar, Rita

From: Kumar, Rita
Sent: Friday, June 12, 2015 4:27 PM
To: 'DJones@hartz.com'
Subject: FW: 2596-181 revised csf
Attachments: image2015-06-12-162042.pdf

Dear David: Please see attached. This action is now complete.

Regards,

Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 11, 2015

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: CSF Amendment –Revised Basic CSF
Product Name: Hartz Ref # 146
EPA Registration Number: 2596-181
Application Date: January 22, 2015
Decision Number: D503215

Dear Mr. Jones:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/22/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Rita Kumar by phone at (703) 308-8291 or via email at kumar.rita@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Venus Eagle", with a long horizontal flourish extending to the right.

Venus Eagle
Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

2596-181



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

January 22, 2015

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Minor Formulation Amendment; Hartz Reference #146, EPA Reg. No. 2596-181

Dear Sir/Madam,

Please find enclosed an application to amend the subject product formulae. The minor amendments are outlined below

- Changed suppliers on inert ingredients
- Fixed minor typos on inert ingredients, match inerts database

Included with this application are two copies of each Confidential Statement of Formula signed and dated and EPA Form 8570-1, all signed and dated January 22, 2015

Thank you for your efforts in supporting this action. Any questions or request for additional information would be welcomed.

Sincerely,

A handwritten signature in dark ink, appearing to be "Heather Masch", written over a horizontal line.

Heather Masch
Regulatory Affairs Specialist
Ph. (201) 271-4800, ext. 7036



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-181	2. EPA Product Manager Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #146	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Minor formulation amendment per PR Notice 98-10. (See Attached Explanation) I certify that this notification is consistent with PR Notice 95-1 and EPA regulations at 40 CFR 152.46 and that no other changes have been made to the labeling of this product. I further understand that if this notification is not consistent with the terms of PR Notice 95-1 and 40 CFR 152.46, then this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather Masch	Title Regulatory Specialist	Telephone No. (Include Area Code) 201-271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name Heather Masch	5. Date 1/22/15	

Kumar, Rita

From: Eagle, Venus
Sent: Thursday, April 09, 2015 5:18 PM
To: Kumar, Rita
Subject: FW: Fw: Checking on status of 2 CSFs, alternates for EPA Reg. No.s 2596-180 and 2596-181
Attachments: EPA 2596-180 and -181 csf Minor amends 2015 Jan 22.pdf

Hi Rita,

This notification came in on my Birthday (so I know I wasn't here) and apparently the hard copy never made it to my desk! So the registrant kindly submitted the electronic version. I just pulled these down in OPPIN and assigned them to you since it is an imidacloprid action. These appear very easy, so if you would put this to the top of your list to knock out, I would appreciate it. Have a great weekend.

Thanks,

Venus

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Monday, April 06, 2015 3:26 PM
To: Eagle, Venus
Subject: Re: Fw: Checking on status of 2 CSFs, alternates for EPA Reg. No.s 2596-180 and 2596-181

Hi Venus,

Thank you for the call back. First, belated Happy Birthday! 21 at last right?

Please find attached a scan of the original submissions. Both are in the one scan. Any help you can give us on getting approval would be appreciated.

Best regards,

Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: David L. Jones/ML1
To: "Eagle, Venus" <Eagle.Venus@epa.gov>,
Date: 04/06/2015 10:52 AM
Subject: Fw: Checking on status of 2 CSFs, alternates for EPA Reg. No.s 2596-180 and 2596-181

Good morning,
I was follow up to see if I can get the status on this filing please?
Thank you for the help,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

----- Forwarded by David L. Jones/ML1 on 04/06/2015 10:51 AM -----

From: "Davis, Kable" <Davis.Kable@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Cc: "Eagle, Venus" <Eagle.Venus@epa.gov>
Date: 03/20/2015 10:31 AM
Subject: RE: Checking on status of 2 CSFs, alternates for EPA Reg. No.s 2596-180 and 2596-181

Hi Dave –

Thanks for the email and question. I can't believe it is the first day of spring and it's snowing!

I'm copying Venus Eagle on this email, since both products are on her team. I checked our system and it looks like both actions were received by the Agency on January 26, 2015. Venus should be able to provide more of an update.

Have a fun/relaxing weekend!
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: DJones@hartz.com [<mailto:DJones@hartz.com>]
Sent: Friday, March 20, 2015 8:43 AM
To: Davis, Kable
Subject: Checking on status of 2 CSFs, alternates for EPA Reg. No.s 2596-180 and 2596-181

Good morning,
Getting ready for Spring to start with 2 to 5 inches of snow to shovel this afternoon at my house! I must have missed something in school about Spring?
I know Autumn M. is out on vacation or close to leaving so I did not want to bother her with this and sorry to trouble you, but could you forward this to someone that can let me know if these CSF notifications have been cleared? It is only a change of source on one inert, two nonfood topical flea and tick products for pets. It was mailed January 22, 2015. My staff member that submitted it is no longer here and I do not have access to her prior e-mail history.
Again apologize for the question, but they want to order the material for a trial batch. Any information we could get soon would be appreciated.
Thank you and have a great weekend.
Dave

PROCESSING REQUEST

Reg # 2596 - 181

Decision # 500401

Description:

Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☒ Notification Dated 3/3/2015

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melody Banks

Division: IVB3

Phone: 3055413

Date: 3/19/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 3, 2015

Ms. Heather Masch
Regulatory Affairs Specialist
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Label Notification per PRN 98-10 – Alternate Brand Names
Product Name: Hartz Ref #146
EPA Registration Number: 2596-181
Application Date: November 5, 2014
Decision Number: 500401

Dear Ms. Masch:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records. The alternate brand names: Hartz® Advanced™ for Cats, Hartz® Advanced™ for Kittens, Hartz® Advanced™ for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Cats, Hartz® Advanced™ Flea Treatment for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Kittens, Advanced™ Flea Treatment for Cats, Advanced™ Flea Treatment for Cats and Kittens, Advanced™ Flea Treatment for Kittens has been added to the product record.

If you have any questions, you may contact Melody Banks at 703 305 5413 or via email at Banks.Melody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Venus Eagle", with a long horizontal line extending to the right.

Venus Eagle, Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Registration Section 3

Product # 25067 Milestone Email

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Notification Fee For Service: ☐ Yes ☒ No

Company: 2506 THE HARTZ MOUNTAIN CORPORATION

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2506-121 Product Name: HARTZ REFERENCE # 146

Overload:

We Sp: We Sp Product Name:

Application Date: 05-Nov-2014 ORP Rec'd Date: 23-Feb-2015

Front End Date: 23-Feb-2015 Risk Manager Send Date: 23-Feb-2015

FTS Due Date: Registered Due Date:

ORP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Label Notification - ADNs (3)

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content:

Print Label

Enter More Information

Tracking

Handwritten signature



400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688. 201/271-4800

November 5, 2014

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)
RE: Hartz Ref #146
EPA Reg. No. 2596-181
Addition of brand names per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add new additional brand names for the product **Hartz Ref #146, EPA Reg. No. 2596-181.**

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1) and;
- ^{one} ~~Three~~ copies of the proposed notification label.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800 ext. 7036 or hmasch@hartz.com.

Sincerely,

Heather Masch
Regulatory Affairs Specialist



Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-181	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Ref #146	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar to NOTIFICATION and labeling to: EPA Reg. No. <u>MAR - 3 2014</u> Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Addition of alternate brand names per PR Notice 98-10"

"This notice is consistent with the provisions of PR Notices 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather Masch	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 201-271-4800, ext. 7036
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Heather Masch	5. Date 11/5/14	

[FRONT PANEL]

Hartz® Reference # 146

Alternate Brand Names

Hartz® Advanced™ for Cats

Hartz® Advanced™ for Kittens

Hartz® Advanced™ for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Cats

Hartz® Advanced™ Flea Treatment for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Kittens

Advanced™ Flea Treatment for Cats

Advanced™ Flea Treatment for Cats and Kittens

Advanced™ Flea Treatment for Kittens

Hartz First Defense Max for Cats [& or Kittens]

Hartz First Defense Advanced PLUS for Cats [& or Kittens]

Hartz First Defense Advanced PRO for Cats [& or Kittens]

Hartz First Defense Evolution for Cats [& or Kittens]

Hartz First Defense Guardian for Cats [& or Kittens]

Hartz Generic Topical Treatment for Cats [& or Kittens]

Hartz Generic Flea Topical for Cats [& or Kittens]

Hartz Generic for Cats [& or Kittens]

Hartz First Defense ADVANCED for Cats [& or Kittens]

Hartz ADVANCE PRO Flea Treatment for Cats [& or Kittens]

Hartz UltraGuard Sentinel for Cats [& or Kittens]

Hartz UltraGuard Sentinel MAX for Cats [& or Kittens]

Hartz UltraGuard Sentinel PLUS for Cats [& or Kittens]

Hartz UltraGuard Sentinel PRO for Cats [& or Kittens]

Hartz UltraGuard Defender for Cats [& or Kittens]

Hartz UltraShield for Cats [& or Kittens]

Hartz ImidaShield II for Cats [& or Kittens]

Hartz ImidaShield II MAX for Cats [& or Kittens]

Hartz ImidaShield II PLUS for Cats [& or Kittens]

Hartz ImidaShield II PRO for Cats [& or Kittens]

Hartz ImidaShield for Cats [& or Kittens]

Hartz ImidaShield MAX for Cats [& or Kittens]

Hartz ImidaShield PLUS for Cats [& or Kittens]

Hartz ImidaShield PRO for Cats [& or Kittens]

Hartz ImidaGuard II for Cats [& or Kittens]

Hartz ImidaGuard II MAX for Cats [& or Kittens]

Hartz ImidaGuard II PLUS for Cats [& or Kittens]

NOTIFICATION

MAR - 3 2014

Hartz ImidaGuard II PRO for Cats [& or Kittens]
Hartz ImidaGuard for Cats [& or Kittens]
Hartz ImidaGuard MAX for Cats [& or Kittens]
Hartz ImidaGuard PLUS for Cats [& or Kittens]
Hartz ImidaGuard PRO for Cats [& or Kittens]
Hartz ProCare for Cats [& or Kittens]
Hartz FirstCare for Cats [& or Kittens]

[Each of the above brands will be packaged in the weight classes designated below:]

For use ONLY on Cats 8 weeks and Older and Weighing 2 to 5 lbs.

or Weighing 5 to 9 lbs.

or Weighing Over 9 lbs.

[FRONT PANEL (cont.)]

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
Other Ingredients.	90.44%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautionary statements and directions for use.

NET CONTENTS:

[Large clear picture of a cat in appropriate weight range on front panel to be included]

For use ONLY on Cats 8 weeks and Older and Weighing:	Net Contents
2 to 5 lbs.	0.031 fl. oz. (0.92 ml), Contains 4 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.056 fl. oz. (1.6 ml), Contains 4 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.108 fl. oz. (3.2 ml), Contains 4 tubes, each 0.027 fl. oz. (0.8 ml)

For use ONLY on Cats 8 weeks and Older and Weighing:	
2 to 5 lbs.	0.046 fl. oz. (1.38 ml), Contains 6 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.084 fl. oz. (2.4 ml), Contains 6 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.162 fl. oz. (4.8 ml),

Hartz[®] Reference #146

EPA Reg. No.: 2596-181

Version: Nov 4, 2014

MASTER LABEL

	Contains 6 tubes, each 0.027 fl. oz. (0.8 ml)
--	---

[BACK PANEL]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment or advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than [2 lbs.; 5 lbs.; 9 lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

[BACK PANEL (cont.)]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

RESTRICTIONS

USE ONLY ON CATS OR KITTENS 8 WEEKS AND OLDER WEIGHING [2 to 5 lbs.; 5 to 9 lbs.; Over 9 lbs.]

DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS

DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT ON ANY CAT

DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

DO NOT USE ON CATS WEIGHING LESS THAN 2 LBS. [this line only required on product labeled for use on cats weighing 2 to 5 lbs.]

Side Effects (Cats): Monitor your cat after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call, 1-800-275-1414.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (cont.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube And Application To Animal]

[OPTION 1:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this **product in your pet's eyes, or allow your pet to ingest this product**. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**.
3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this **product in your pet's eyes, or allow your pet to ingest this product**. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[BACK PANEL (cont.)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-274-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-

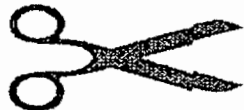
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[INSTRUCTIONS FOR BLISTER PACK]

HOW TO OPEN



[OPTION 1:]

1. Being careful not to cut close to the blister cavities, take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

INDIVIDUAL TUBE TEXT

(Product name)

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]

ONLY FOR USE ON CATS AND KITTENS 8 WEEKS OR OLDER WEIGHING 2 to 5 lbs. -

0.0078 fl. oz. (0.23 ml)

or 5 to 9 lbs. - 0.014 fl. oz. (0.4 ml)

or 9 lbs. and Over - 0.027 fl. oz. (0.8 ml)

9.10% Imidacloprid

0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read The Entire Label Before Use

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

(Lot no. is heat stamped in tube crimp – required on each)

OPTIONAL/ALTERNATE LABEL TEXT

For use on cats and kittens 8 weeks of age and older

(Insert Product Name) contains Imidacloprid, [and an/the] [insect growth regulator] [IGR]
[Pyriproxyfen]

A single topical application remains effective for up to [4 weeks] [1 month]

Convenient, easy-to-apply topical solution

Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]

Once a month topical flea prevention and treatment for cats 8 weeks of age or older

(Insert Product Name) is indicated for the prevention and treatment of fleas on cats 8 weeks of age and older

For the prevention and treatment of flea infestations on cats

One treatment prevents further flea infestations for up to [4 weeks] [1 month] [30 days]

Kills fleas and continues to prevent infestations for up to [four weeks] [a month] [30 days]

Kills larval stages of fleas following contact with [a/an] [Product Name] treated cat

Stops existing flea infestations by killing adult fleas

Effectively breaks the flea life cycle

[Kills] [Controls] life stages

Comprehensive flea prevention and treatment

2-way flea protection ([kills] [controls]) adults and eggs

Treatment of cats with [Product Name] kills fleas and that may cause flea allergy dermatitis [FAD] [or flea bite hypersensitivity]

Flea adulticide and ovicide

Kills flea eggs

Controls flea problems

Provides flea protection

Controls existing fleas and flea eggs plus [and] [prevents] future flea infestations

[Brand Name] may be used year-round for flea [prevention] [protection]

Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation

Monthly use of [Product Name] on cats kills fleas that may cause ([flea allergy dermatitis] [flea bite hypersensitivity])

Controls existing flea infestations on your cat and prevents further infestations

Prevents fleas on treated cats from infesting (reinfesting)

Fragrance-free

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs) from developing

Kills fleas (and flea eggs) [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation (reinfestation)

Effective and convenient topical treatment

(With) patented applicator

Easy spot on topical applicator
Remains effective even after bathing or water immersion.
(Product Name) remains effective even after bathing or water immersion.

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II
(or Advantage® II)
Contains the (same) active ingredients used in Bayer Advantage® II (or Advantage® II)
(products)
Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II
(or Advantage® II) (brand products)
[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered
trademark of Bayer Healthcare LLC.

Only for cats and kittens 8 weeks of age or older
For cats and kittens 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose
First month, second month, third month, fourth month, fifth month, sixth month
Value pack
[1] [2] [3] [4] [5] [6] month supply
[4 or 6] monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(4 or 6) Pro-cision Flo® Applicator(s) (included)
(4 or 6) Pro-glide® Applicator(s) (included)
(Pro-cision Flo® Applicator)
(Pro-Glide® Applicator)
Featuring [Pro-cision Flo®] [Pro-Glide®] Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Convenient to use

After application, the treated area may appear wet for up to 24 hours
To help remind you when you last applied treatment, simply write in the date when each dose is
applied:

First Dose _____
Second Dose _____
Third Dose _____
Fourth Dose _____
Fifth Dose _____
Sixth Dose _____

Material Sent for Data Extraction

Reg. # 2596-181

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification Dated 12/11/2014

☐ New CSF(s) Dated _____

☐ Other: _____

☒ Decision #: 498025

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melody Banks

Phone: 305 5413 Division: TVB3

Date: 2/11/2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 11, 2014

Ms. Heather Masch
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Label Notification per PRN 98-10 – Nine Alternate Brand Names
Product Name: HARTZ Ref#146
EPA Registration Number: 2596-181
Application Date: November 10, 2014
Decision Number: 498025

Dear Ms. Masch:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand names: Hartz® Advanced™ for Cats, Hartz® Advanced™ for Kittens, Hartz® Advanced™ for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Cats, Hartz® Advanced™ Flea Treatment for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Kittens, Advanced™ Flea Treatment for Cats, Advanced™ Flea Treatment for Cats and Kittens, and Advanced™ Flea Treatment for Kittens has been added to the product records

If you have any questions, you may contact Melody Banks at 703 305 5413 or via email at banks.melody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "VE", followed by a horizontal line.

Venus Eagle, Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

[FRONT PANEL]

Hartz® Reference # 146

Alternate Brand Names

Hartz® Advanced™ for Cats

Hartz® Advanced™ for Kittens

Hartz® Advanced™ for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Cats

Hartz® Advanced™ Flea Treatment for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Kittens

Advanced™ Flea Treatment for Cats

Advanced™ Flea Treatment for Cats and Kittens

Advanced™ Flea Treatment for Kittens

Hartz First Defense Max for Cats [& or Kittens]

Hartz First Defense Advanced PLUS for Cats [& or Kittens]

Hartz First Defense Advanced PRO for Cats [& or Kittens]

Hartz First Defense Evolution for Cats [& or Kittens]

Hartz First Defense Guardian for Cats [& or Kittens]

Hartz Generic Topical Treatment for Cats [& or Kittens]

Hartz Generic Flea Topical for Cats [& or Kittens]

Hartz Generic for Cats [& or Kittens]

Hartz First Defense ADVANCED for Cats [& or Kittens]

Hartz ADVANCE PRO Flea Treatment for Cats [& or Kittens]

Hartz UltraGuard Sentinel for Cats [& or Kittens]

Hartz UltraGuard Sentinel MAX for Cats [& or Kittens]

Hartz UltraGuard Sentinel PLUS for Cats [& or Kittens]

Hartz UltraGuard Sentinel PRO for Cats [& or Kittens]

Hartz UltraGuard Defender for Cats [& or Kittens]

Hartz UltraShield for Cats [& or Kittens]

Hartz ImidaShield II for Cats [& or Kittens]

Hartz ImidaShield II MAX for Cats [& or Kittens]

Hartz ImidaShield II PLUS for Cats [& or Kittens]

Hartz ImidaShield II PRO for Cats [& or Kittens]

Hartz ImidaShield for Cats [& or Kittens]

Hartz ImidaShield MAX for Cats [& or Kittens]

Hartz ImidaShield PLUS for Cats [& or Kittens]

Hartz ImidaShield PRO for Cats [& or Kittens]

Hartz ImidaGuard II for Cats [& or Kittens]

Hartz ImidaGuard II MAX for Cats [& or Kittens]

Hartz ImidaGuard II PLUS for Cats [& or Kittens]

Hartz ImidaGuard II PRO for Cats [& or Kittens]
Hartz ImidaGuard for Cats [& or Kittens]
Hartz ImidaGuard MAX for Cats [& or Kittens]
Hartz ImidaGuard PLUS for Cats [& or Kittens]
Hartz ImidaGuard PRO for Cats [& or Kittens]
Hartz ProCare for Cats [& or Kittens]
Hartz FirstCare for Cats [& or Kittens]

[Each of the above brands will be packaged in the weight classes designated below:]

For use ONLY on Cats 8 weeks and Older and Weighing 2 to 5 lbs.

or Weighing 5 to 9 lbs.

or Weighing Over 9 lbs.

[FRONT PANEL (cont.)]

ACTIVE INGREDIENTS:

Imidacloprid9.10%
Pyriproxyfen0.46%
Other Ingredients. 90.44%
Total100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautionary statements and directions for use.

NET CONTENTS:

[Large clear picture of a cat in appropriate weight range on front panel to be included]

For use ONLY on Cats 8 weeks and Older and Weighing:	Net Contents
2 to 5 lbs.	0.031 fl. oz. (0.92 ml), Contains 4 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.056 fl. oz. (1.6 ml), Contains 4 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.108 fl. oz. (3.2 ml), Contains 4 tubes, each 0.027 fl. oz. (0.8 ml)

For use ONLY on Cats 8 weeks and Older and Weighing:	
2 to 5 lbs.	0.046 fl. oz. (1.38 ml), Contains 6 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.084 fl. oz. (2.4 ml), Contains 6 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.162 fl. oz. (4.8 ml),

	Contains 6 tubes, each 0.027 fl. oz. (0.8 ml)
--	---

[BACK PANEL]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment or advice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than [2 lbs.; 5 lbs.; 9 lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

[BACK PANEL (cont.)]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

RESTRICTIONS

USE ONLY ON CATS OR KITTENS 8 WEEKS AND OLDER WEIGHING [2 to 5 lbs.; 5 to 9 lbs.; Over 9 lbs.]

DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS

DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT ON ANY CAT

DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

DO NOT USE ON CATS WEIGHING LESS THAN 2 LBS. [this line only required on product labeled for use on cats weighing 2 to 5 lbs.]

Side Effects (Cats): Monitor your cat after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call, 1-800-275-1414.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (cont.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube And Application To Animal]

[OPTION 1:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your pet's eyes, or allow your pet to ingest this product. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**.
3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your pet's eyes, or allow your pet to ingest this product. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.* Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[BACK PANEL (cont.)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-274-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[INSTRUCTIONS FOR BLISTER PACK]

HOW TO OPEN



[OPTION 1:]

1. Being careful not to cut close to the blister cavities, take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

INDIVIDUAL TUBE TEXT

(Product name)

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]

ONLY FOR USE ON CATS AND KITTENS 8 WEEKS OR OLDER WEIGHING 2 to 5 lbs. -

0.0078 fl. oz. (0.23 ml)

or 5 to 9 lbs. - 0.014 fl. oz. (0.4 ml)

or 9 lbs. and Over - 0.027 fl. oz. (0.8 ml)

9.10% Imidacloprid

0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read The Entire Label Before Use

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

(Lot no. is heat stamped in tube crimp – required on each)

OPTIONAL/ALTERNATE LABEL TEXT

For use on cats and kittens 8 weeks of age and older

(Insert Product Name) contains Imidacloprid, [and an/the] [insect growth regulator] [IGR]
[Pyriproxyfen]

A single topical application remains effective for up to [4 weeks] [1 month]

Convenient, easy-to-apply topical solution

Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]

Once a month topical flea prevention and treatment for cats 8 weeks of age or
older

(Insert Product Name) is indicated for the prevention and treatment of fleas on cats 8 weeks
of age and older

For the prevention and treatment of flea infestations on cats

One treatment prevents further flea infestations for up to [4 weeks] [1 month] [30 days]

Kills fleas and continues to prevent infestations for up to [four weeks] [a month] [30 days]

Kills larval stages of fleas following contact with [a/an] [Product Name] treated cat

Stops existing flea infestations by killing adult fleas

Effectively breaks the flea life cycle

[Kills] [Controls] life stages

Comprehensive flea prevention and treatment

2-way flea protection ([kills] [controls]) adults and eggs

Treatment of cats with [Product Name] kills fleas and that may cause flea allergy dermatitis
[FAD] [or flea bite hypersensitivity]

Flea adulticide and ovicide

Kills flea eggs

Controls flea problems

Provides flea protection

Controls existing fleas and flea eggs plus [and] [prevents] future flea infestations

[Brand Name] may be used year-round for flea [prevention] [protection]

Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation

Monthly use of [Product Name] on cats kills fleas that may cause ([flea allergy dermatitis] [flea
bite hypersensitivity])

Controls existing flea infestations on your cat and prevents further infestations

Prevents fleas on treated cats from infesting (reinfesting)

Fragrance-free

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs) from developing

Kills fleas (and flea eggs) [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation (reinfestation)

Effective and convenient topical treatment

(With) patented applicator

Easy spot on topical applicator
Remains effective even after bathing or water immersion.
(Product Name) remains effective even after bathing or water immersion.

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II
(or Advantage® II)
Contains the (same) active ingredients used in Bayer Advantage® II (or Advantage® II)
(products)
Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II
(or Advantage® II) (brand products)
[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered
trademark of Bayer Healthcare LLC.

Only for cats and kittens 8 weeks of age or older
For cats and kittens 8 weeks of age or older

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose
First month, second month, third month, fourth month, fifth month, sixth month
Value pack
[1] [2] [3] [4] [5] [6] month supply
[4 or 6] monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(4 or 6) Pro-cision Flo® Applicator(s) (included)
(4 or 6) Pro-glide® Applicator(s) (included)
(Pro-cision Flo® Applicator)
(Pro-Glide® Applicator)
Featuring [Pro-cision Flo®] [Pro-Glide®] Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Convenient to use

After application, the treated area may appear wet for up to 24 hours
To help remind you when you last applied treatment, simply write in the date when each dose is
applied:

First Dose _____
Second Dose _____
Third Dose _____
Fourth Dose _____
Fifth Dose _____
Sixth Dose _____

Receipt For Section 3

IS: 2500200 Warehouse Email:

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Notification Fee For Service: ☐ Yes ☒ No

Company: 2500 THE HARTZ MOUNTAIN CORPORATION

Risk Manager: Registration Division, Risk Management Team 1

Product #: 2500-101 Product Name: HARTZ REFERENCE # 140

Overhead:

Mo Year: We See Product Name:

Application Date: 13-Nov-2014 OPR Rec'd Date: 12-Nov-2014

Front End Date: 12-Nov-2014 Risk Manager Sent Date: 12-Nov-2014

FFS Due Date: Negotiated Due Date:

OPR Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: Label Notification - ADNs (3)

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Receipt Content:

Methody



400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688. 201/271-4800

November 10, 2014

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)
RE: Hartz Ref #146
EPA Reg. No. 2596-181
Addition of brand names per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add new additional brand names for the product **Hartz Ref #146, EPA Reg. No. 2596-181**.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1) and;
- Three copies of the proposed notification label.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7036 or hmasch@hartz.com.

Sincerely,

A handwritten signature in black ink, appearing to be "Hmasch", written over a horizontal line.

Heather Masch
Regulatory Affairs Specialist



Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-181	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Ref #146	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Addition of alternate brand names per PR Notice 98-10"

"This notice is consistent with the provisions of PR Notices 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather Masch	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 201-271-4800, ext. 7036
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Specialist	
4. Typed Name Heather Masch	5. Date 11/10/14	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

December 16, 2014

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

RE: Hartz Ref #146
EPA Reg. No. 2596-181
Final Printed Label Submission

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting final printed labels for the product **Hartz Ref #146, EPA Reg. No. 2596-181**.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1) and;
- Two copies of the final printed label

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7036 or hmasch@hartz.com.

Sincerely,

A handwritten signature in black ink, appearing to be "H Masch", written over a horizontal line.

Heather Masch
Regulatory Affairs Specialist



Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-181	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Reference #146	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Final Printed Product Labels

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

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Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamp-I)
2. Signature 		3. Title Regulatory Affairs Specialist			
4. Typed Name Heather Masch		5. Date 12/16/14			

185211

Hartz **ADVANCED**[™]
Flea Treatment for **CATS**

For use ONLY on cats
8 weeks and older
weighing
5 to 9 lbs.

CONTAINS
THE SAME ACTIVE
INGREDIENTS USED IN
ADVANTAGE[®] II[®] PRODUCTS

Hartz

ADVANCED[™]

Flea Treatment for **CATS**

For use ONLY on cats
8 weeks and older
weighing

5 to 9 lbs.



kills flea eggs



kills fleas



kills life stages

**4 Monthly
Treatments**

Kills fleas for 30 days



ACTIVE INGREDIENTS:

Imidacloprid 9.10%
Pyriproxyfen 0.46%
Other Ingredients 90.44%
TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION:

See back panel for Precautionary
Statements and Directions for Use.

NET CONTENTS:

0.056 fl. oz. (1.6 mL),
Contains 4 tubes,
each 0.014 fl. oz. (0.4 mL)

*Hartz Advanced[™] Flea Treatment for Cats
is not manufactured by or distributed by
Bayer. Advantage[™] II is a registered
trademark of Bayer Healthcare, L.L.C.

Hartz **ADVANCED**[™] Flea Treatment for **CATS**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION:

Harmful if swallowed. Causes moderate eye
irritation. Avoid contact with eyes
or clothing. Wash hands thoroughly with soap
and warm water after handling. Keep out of
reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens
under 8 weeks of age or weighing less than 5 lbs. As
with any product, consult your veterinarian before
using this product on debilitated, aged, pregnant or
nursing cats. Individual sensitivities, while rare, may
occur after using ANY pesticide product for cats. If
signs persist, or become more severe, consult a
veterinarian immediately. If your cat is on medication,
consult your veterinarian before using this or any
other product.

FIRST AID

Have the product container or label with you
when calling a poison control center or doctor, or
going for treatment. For medical emergencies or
consumer questions call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or
doctor immediately for treatment advice. Have
person sip a glass of water if able to swallow.
Do not induce vomiting unless told to do so by a
poison control center or doctor. Do not give
anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and
gently with water for 15-20 minutes. Remove
contact lenses, if present, after the first 5
minutes, then continue rinsing eye. Call a poison
control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off
contaminated clothing. Rinse skin immediately
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poison control center or doctor for treatment or
advice.

For more information call our experts at
1-800-275-1414 (weekdays, 9 am - 5 pm E.S.T.)
EPA Reg. No. 2596-181 EPA Est. No. 2596-OH-1
Hartz[®] and other trademarks are trademarks of
The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation,
400 Plaza Drive, Secaucus, NJ 07094 (USA)



0 32700 14736 5 RM112581

For the Prevention and Treatment of Flea Infestations on Cats

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product
in a manner inconsistent with its labeling.
Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

RESTRICTIONS

USE ONLY ON CATS OR KITTENS
8 WEEKS AND OLDER WEIGHING
5 to 9 lbs.

DO NOT USE ON OTHER ANIMALS.

DO NOT EXCEED LABELED DOSAGE
AMOUNT FOR CATS.

DO NOT APPLY MORE
THAN ONE (1) TUBE PER
TREATMENT ON ANY CAT.

DO NOT HAVE CONTACT
OR ALLOW CHILDREN TO
HAVE CONTACT WITH
TREATED AREA UNTIL
COMPLETELY DRY.

Side Effects (Cats): Monitor your cat after application. Side
effects, although very rare, may include signs of skin irritation such as
redness, scratching, or other signs of discomfort. Gastrointestinal
signs such as hypersalivation, vomiting or diarrhea have also been
reported. If these or other side effects (such as lethargy) occur,
consult your veterinarian or call, 1-800-275-1414.

HOW TO APPLY

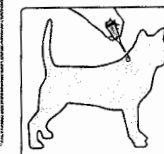


1) Remove one
applicator tube
from the
package.

2) Hold applicator tube in an
upright position facing away from
you and your pet's face and eyes.



3) Twist
dispensing tip
clockwise
about 1/2 turn
while pushing
down to break the tube's seal. Do
not remove the dispensing tip.



4) Part the hair on the neck at the base of the
skull until the skin is visible. Place the tip of
the tube on the skin and squeeze the tube to
expel the entire contents directly on the skin.
Do not get this product in your pet's eyes,
or allow your pet to ingest this product.
The product is bitter tasting and salivation
may occur for a short time if the pet licks
the product immediately after treatment.
Treatment at the base of the skull will

minimize the opportunity for the cat to lick the product. Do not allow the
product to run off.

5) Discard empty tube as described in the Storage and Disposal section.

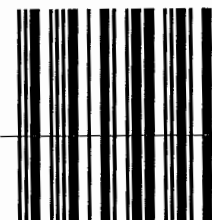
6) Under normal conditions this product is effective for a month. However, in
case of severe flea infestation, retreatment may be necessary earlier than
four (4) weeks. On cats, do not retreat more often than once every seven (7)
days. After flea control is attained, return to a monthly treatment schedule.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

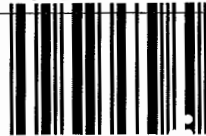
PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. If empty: Do not reuse or refill this container. Place in
trash or offer for recycling if available. If partly filled: Call your local solid waste
agency or 1-800-275-1414 for disposal instructions. Never place unused product
down any indoor or outdoor drain.



112581

185211



Hartz ADVANCED[™] Flea Treatment for CATS

For use on cats 8 weeks and older
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5 to 9 lbs.

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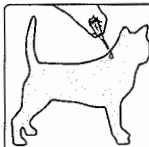


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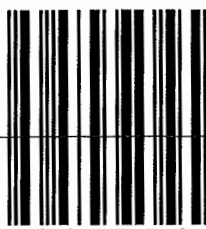


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